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December 12, 2000

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of Leslie Lars IVERSEN
U.S. Application No. 09/529,537
Filed on June 19, 2000
ANALGESIC COMPOSITIONS

Art Unit 1614

(Atty. Docket No. P 24,002 USA)

CERTIFICATE OF MAILING

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to Assistant Commissioner for Patents, Washington, D.C. 20231, on Tuesday, December 12, 2000.

A handwritten signature of Gene J. Yao.

Gene J. Yao

Assistant Commissioner for Patents
Washington, DC 20231

SUBMISSION OF INFORMATION
DISCLOSURE STATEMENT PURSUANT TO 37 CFR §1.97(b)

Sir:

Pursuant to 37 CFR §1.97(b), enclosed herewith is "Form PTO-1449 Modified". The status of the present application is that applicant is awaiting a first Action on the merits.

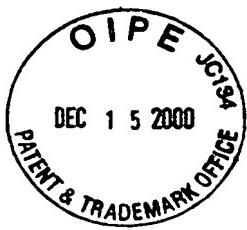
Summary of the Invention

The present invention relates to a composition comprising: (A) an opioid-potentiating amount of a cholecystokinin-(hereinafter "CCK") antagonist; (B) an analgesic amount of an opioid; and (C) a pharmaceutically-acceptable biphasic carrier comprising an organic phase and a hydrophilic phase. It is believed that CCK antagonizes opiate action and plays a role in the development of tolerance to opioid analgesia. It is believed also that a blockade of CCK receptors by CCK-antagonists may reverse or prevent the development of opiate tolerance in a patient and potentiate the analgesic effects of opioids. Accordingly, the present invention involves a composition in which CCK-antagonist is used as an effective supplement to opioid administration.

The invention of the present application is defined in the following claim forms: (A) a pharmaceutical formulation which comprises an opioid-potentiating amount of a CCK-antagonist, an analgesic amount of an opioid, and a pharmaceutically-acceptable biphasic carrier comprising an organic phase comprising a glyceride derivative and a hydrophilic phase; and (B) a method of treating chronic and neuropathic pain comprising administering to a patient in need thereof the pharmaceutical formulation described in (A).

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The Publications

Documents AG to AN on Sheet 1 and AB to AC on Sheet 2 relate to CCK-
antagonists.

Document AA on Sheet 2 relates to CCK.

Document AM on Sheet 1 is an equivalent of EP 0,617,621.

Document AN on Sheet 1 is an equivalent of EP 0,652,871.

Documents AA and AO to AQ on Sheet 1 were communicated previously to the Patent Office by the International Bureau of WIPO. Accordingly, applicant has not included copies of these publications. However, applicant will provide copies of the publications to the Examiner upon the Examiner's request.

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Application No. 09/529,537



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The Commissioner is hereby authorized to charge any fee associated with this communication to Deposit Account No. 19-5425. A duplicate of this letter is attached.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Gene J. Yao".

Gene J. Yao, Esquire
Registration No. P-47,193

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